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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,897	11/02/2001	Gerhard Kraft	930008-2030	9265

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EXAMINER

EL SHAMMAA, MARY A

ART UNIT	PAPER NUMBER
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2881

DATE MAILED: 05/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,897

Applicant(s)

KRAFT ET AL.

Examiner

Mary A. El-Shammaa

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 19, 20, 22-28 is/are rejected.
- 7) ☒ Claim(s) 18 and 21 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11-02-01 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: 4, 12, 14, 17, 21, 22, and 26. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-10, 19, 20, and 22-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Nishihara et al. (5,039,867).

Regarding claims 1, 4, 5, and 19, Nishihara et al. discloses in FIGS. 27 and 34 an ion beam scanning system and method having an ion source, and ion accelerator system (not shown) that can obtain a maximum depth of penetration, and an ion beam guidance system comprising an ion beam outlet window for a converging centered ion beam, and a mechanical alignment system for the target volume to be scanned, characterized in that the scanning system (702) comprises energy absorption means (709) that are arranged in the ion beam path between the target volume and the ion beam outlet window transverse to the center of the ion beam and comprises at least two absorber wedges (601a, 601b) that can be displaced transverse to the center of the ion beam, a linear motor (602a, 602b) for rapid driving of the absorber wedges and beam-intensity-controlled depth-scanning with transverse displacement of the energy absorption means, so that depth-staggering scanning of volume elements of a tumor tissue can be carried out in rapid succession (Col. 17, Lines 1-44, Col. 18, Lines 4-24).

Regarding claims 2, 3, and 20, Nishihara et al. discloses in FIGS. 35 and 36 a scanning system comprising an electronic control system (711) for the linear drive of the absorber wedges (709) and includes an ionization chamber (710, wherein the dose monitor performs the function of an ionization chamber according to the present invention) for measuring the particle rate of the beam and moves the absorber wedges, and the target volume is characterized in that it is a tumor tissue surrounded by healthy tissue, wherein the depth of penetration of the ion beam is determined by the energy of the ions in the ion beam (701) and the deepest region of the tumor

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tissue (708) can be reached by means of the variable acceleration of the ions (Col. 18, Lines 40-63).

Regarding claims 6-10, Nishihara et al. discloses in FIGS. 11 and 17 a system comprising an edge-delimitation device (203, 405) having displaceable shutter elements (205, 207) between the target volume (202, 404) and the energy absorption means (407), edge shutters that can be adjusted separately in the manner of an iris diaphragm in order to delimit some of the edge of the ion beam, and a patient table (shown, but not labeled in Figure 11) that carries the target volume (202, 404) and that can be displaced in a plane transverse to the ion beam (401) in two directions of coordinates during an irradiation procedure and has deflection magnets (shown in Figure 17 and labeled "X") that deflect the beam transverse to the lateral direction of the table (Col. 12, Lines 1-58, Col. 13, Lines 1-3 and 61-68, Col. 14, Lines 28-36, Col. 15, Lines 1-10).

Regarding claims 22-26, Nishihara et al. discloses in FIGS. 32 and 39 numerous ways to scan the target volume including continuous scanning, scanning in the depth direction being effected in columns, stepwise scanning, scanning continuously in the depth direction and stepwise in the lateral and longitudinal directions, and continuous scanning in the depth and lateral direction, and stepwise in the longitudinal direction (Col. 19, Lines 1-48). The apparatus disclosed by Nishihara et al. allows for adjustments of the scanning to be either continuous or stepwise, or a combination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nishihara et al..

Nishihara et al. discloses the claimed invention except for the ionization chamber being located upstream of the energy absorption means. It would have been obvious to one having ordinary skill in the art at the time the invention was made to position the ionization chamber upstream of the energy absorption means, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, USPQ 167.

Claims 12-17, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishihara et al. in view of Pu (6,034,377).

Nishihara et al. discloses an ion beam scanning system that comprises a patient table that can be displaced in a lateral direction transverse to an ion beam, as well as energy absorption means comprising at least two absorber wedges. Nishihara et al. does not disclose a rotating gantry system nor does Nishihara et al. disclose the target volume carrier remaining stationary during irradiation. Pu discloses in FIGS. 5 and 10 a beam scanning system comprising an accelerator (1), a beam guidance system (3), a scanning system (33, 35) comprising energy absorption means (21), deflection magnets (11, 13, 19), all part of a rotating gantry system with an axis of rotation (29) (Col. 7, Lines 18-67, Col. 8, Lines 58-63). Pu also discloses a system a target volume carrier that remains stationary during irradiation (Col. 8, Lines 34-45). Pu teaches that a stationary target volume carrier reduces irradiation error due to positional changes and allows for a simplification of the structure of the rotational gantry (Col. 8, Lines 34-40 and 58-

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63). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ion beam scanning system disclosed by Nishihara et al. with the teachings of a rotational gantry and a stationary target volume carrier by Pu.

Allowable Subject Matter

Claims 18 and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to teach or fairly suggest an ion beam scanning system having a gantry system wherein the central region of the target volume is arranged upstream of the isocenter by at least one fifth of the radius of the gantry so that the target volume does not lie in the isocenter, and the intensity being adjusted in the range of 10^6 to 10^8 absorbed ions per volume unit during scanning of the target volume.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. (6,256,591), (EP 0 826394), (EP 0 779081).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary A. El-Shammaa whose telephone number is 703.308.0851. The examiner can normally be reached on M-F (8:30am-5:00pm).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John R. Lee can be reached on 703.308.4116. The fax phone numbers for the organization where this application or proceeding is assigned are 703.872.9318 for regular communications and 703.872.9319 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.872.9317.

mae
March 28, 2003



JOHN R. LEE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2800